

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT
LITIGATION

No. 04-MDL-01592

This Document Relates To:

No. 03-CV-11329-MLW

**SURREPLY MEMORANDUM OF BIOGEN IDEC MA, INC. AND GENZYME
CORPORATION IN OPPOSITION TO COLUMBIA UNIVERSITY'S
MOTION TO DISMISS**

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Columbia's 29-page Reply brief asserts entirely new arguments, modifies (yet again) Columbia's previously stated positions, and relies on twenty-six new cases not even cited in its opening brief or in any of the six opposition briefs. Biogen Idec MA Inc. ("Biogen") and Genzyme Corporation ("Genzyme") (collectively "Plaintiffs") accordingly submit this Surreply in opposition to Columbia's Motion to Dismiss.

I. INTRODUCTION

This is no hypothetical dispute. Although Columbia tinkers with the scope of its Covenant Not to Sue ("Covenant") on a weekly basis, it has yet to covenant that it will never seek royalties or damages for infringement arising out of any current or planned future activity of Biogen or Genzyme, much less their affiliates. The goal of Columbia's chameleon-like Covenant is to avoid scrutiny of its '275 patent—if not forever, then at least at this time in this particular court—while extracting every last possible dollar from its invalid, illegally obtained patent. Because Columbia insists upon retaining the ability to collect royalties and damages, however, it cannot avoid scrutiny of its patent.

Plaintiffs here face a situation in which, prior to the onset of this litigation:

- The plaintiffs in these consolidated cases ("MDL Plaintiffs") collectively paid hundreds of millions of dollars in royalties to Columbia under patents that expired in August 2000;
- Columbia filed two lawsuits to enforce its patent rights, pursuing one to a verdict of infringement;
- Columbia came to rely so heavily upon the MDL Plaintiffs' royalty payments that it lobbied Congress for an extension of its patent rights in order to continue the royalty stream;
- Thwarted in its lobbying efforts, Columbia illicitly obtained an extension of its patent rights from the United States Patent and Trademark Office ("Patent Office"), in the form of the '275 patent;

- Through intentional delay, Columbia prevented the '275 patent from issuing until 2002, with the result that it will not expire until 2019, thirty-nine years after the initial patent application was filed; and
- After issuance of the '275 patent, Columbia demanded that the MDL Plaintiffs resume payment of royalties.

Columbia does not dispute that Plaintiffs are currently engaging in and planning to continue activity that potentially infringes the '275 patent, yet is not covered by its Covenant. Aware that the Covenant falls far short of defeating subject matter jurisdiction, Columbia shifts course and now argues that upon these facts there is no justiciable controversy because it claims (1) that it never *expressly* threatened suit with respect to Plaintiffs' current activities; (2) that it will delay *for a limited period of time* any action for infringement, even though potential liability continues to accrue; and (3) that it has not *yet again* terminated Plaintiffs' license agreements.

Columbia contorts the law of declaratory judgment jurisdiction beyond recognition. All that is required to establish jurisdiction is "a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 241 (1937). The declaratory judgment remedy was created to avoid precisely this situation, where:

a patent owner engages in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword.... Guerilla-like, the patent owner attempts extra-judicial patent enforcement with scare-the-customer-and-run tactics that infect the competitive environment of the business community with uncertainty and insecurity.

Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 734–35 (Fed. Cir. 1988)

(emphasis added). This classic quote regarding the need for declaratory judgment sums up this case and explains why it is important that the Court proceed toward the speedy resolution of this important dispute affecting much of the biotechnology industry. See *Minn. Mining & Mfg. Co. v.*

Norton Co., 929 F.2d 670, 673–74 (Fed. Cir. 1991) (“3M”) (district court abused its discretion in dismissing declaratory judgment action). The Supreme Court, in upholding the ability of a licensee to challenge a licensed patent, underscored the importance of resolving disputes such as this one:

Surely the equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain. Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification.

Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969).

In addition to resolving the critical issues currently pending in Plaintiffs’ declaratory judgment claims, this Court will need to decide the underlying validity and enforceability issues in any event. First, Biogen’s parent company, Biogen Idec, Inc., which is excluded from the Covenant and has no license agreement with Columbia, has itself brought suit for a declaratory judgment concerning the ’275 patent. Second, Plaintiffs have asserted new claims against Columbia, which they seek to consolidate with the claims in this action. The Court clearly has subject matter jurisdiction to hear Plaintiffs’ new claims, which sound in contract and tort. These claims, themselves, will require the Court to determine whether the ’275 patent is invalid and unenforceable, such that Columbia’s earlier termination of Plaintiffs’ licenses for failure to pay royalties under the ’275 patent constituted breach of contract and violation of Mass Gen. Laws ch. 93A.

Columbia’s motion to dismiss should be denied without further distraction, so that the parties can return to the merits of the case.

II. ARGUMENT

A. Because the Covenant does not cover Plaintiffs' ongoing or future activity and excludes affiliates, it does not divest the Court of jurisdiction.

Columbia does not dispute the sworn evidence that both Biogen and Genzyme are currently engaged in, and have concrete plans to continue, activities that potentially infringe the '275 patent. Moreover, Columbia does not deny that these activities fall outside of the Covenant. (Reply at 1.)

This posture renders inapposite *Spectronics*, *Super Sack*, and *Amana*, the cases underlying Columbia's Motion to Dismiss. (Biogen Opp. at 19–20.) The cases are clear: where there is potentially infringing activity that falls outside of a covenant not to sue, the covenant does not eliminate declaratory judgment jurisdiction. *See* Biogen Opp. at 20–21; *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1375 (Fed. Cir. 2004) (“[b]y not making a promise not to sue of a breadth equal to its threats,” patentee failed to eliminate reasonable apprehension.); *Fina Research S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1483–84 (Fed. Cir. 1998) (covenant that does not encompass all possible infringement claims does not eliminate licensee's reasonable apprehension of suit); *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 876, 881 (Fed. Cir. 1983) (patentee's affidavit stating that it had no intention of terminating license and bringing suit insufficient to remove licensee's reasonable apprehension of suit); *GFI, Inc. v. Franklin Indus.*, 27 F. Supp. 2d 686, 692 (N.D. Miss. 1998) (where there were plans to make a product that may later be said to infringe, covenant not to sue with respect to current products was insufficient to divest the court of jurisdiction).

Columbia's Covenant is grossly deficient in another respect—it fails to provide any assurance that Columbia will not charge Plaintiffs' corporate affiliates with infringement. (Biogen Opp. at 23–24.) Columbia argues that Plaintiffs' affiliates are irrelevant to this Court's

jurisdictional analysis. (Reply 17–18.) The threat of suit against affiliates, however, is properly considered as part of the “totality of the circumstances,” which takes into account the realities of business life. *See Arrowhead*, 846 F.2d at 736 (giving weight to the possibility of infringement suits against a putative infringer’s customers in the “totality of the circumstances”) (citing *Grafon Corp. v. Hausermann*, 602 F.2d 781 (7th Cir. 1979)); *Bard*, 716 F.2d at 882 (giving weight to the possibility of an infringement suit against a sub-licensee in the “totality of the circumstances”). Indeed, Biogen’s affiliate Biogen Idec Inc. has developed products using cotransformation technology without the benefit of a license from Columbia, and clearly has a reasonable apprehension of suit.

B. Columbia’s conduct creates an actual controversy.

1. *There was an actual controversy at the time the complaint was filed.*

Lacking any argument that the Covenant *eliminates* reasonable apprehension of suit, Columbia argues, for the first time since this suit was filed in July 2003, that Plaintiffs never had any reasonable apprehension of suit in the first place (raising the question of why it issued a covenant not to sue). (Reply at 6.) This newly coined argument is preposterous.

As summarized above, Plaintiffs had a reasonable apprehension of suit at the time they filed the complaint, based upon the scope Columbia had asserted for its patent rights, its claim that Plaintiffs owed royalties, and its willingness to sue for infringement—as well as lobby Congress and pressure the Patent Office—in order to obtain additional royalties. *See, e.g., Dewey & Almy Chem. Co. v. Am. Anode, Inc.*, 137 F.2d 68, 69–70 (3d Cir. 1943) (reasonable apprehension arising from fact that patentee had “publicly asserted such a scope for its patent claims as to embrace the similar methods” practiced by the plaintiff). Columbia received from the MDL Plaintiffs millions of dollars in royalties under predecessor patents whose claims were, at the *very* least, strikingly similar to the claims of the ’275 patent. In the meantime, Columbia

promptly brought two suits for infringement of the earlier patents, pursuing one to an infringement verdict. (Reply at 11.) *See, e.g., Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987) (reasonable apprehension based upon separate trade secret litigation involving the same technology as recently issued patent). When its patents expired, it engaged in Herculean efforts to maintain the stream of royalties from the MDL Plaintiffs, petitioning both Congress and the Patent Office for an extension of its monopoly. Its illegal Patent Office exploits resulted in the issuance of the '275 patent, at which point Columbia informed Plaintiffs that their royalty payments should continue. *See Bard*, 716 F.2d at 881 (demand for royalty payments supports reasonable apprehension of suit).

Columbia's actions since the filing of this suit have done nothing to alter the obvious fact that Columbia has been eagerly and strategically awaiting the day on which it will have the best chance to restart the flow of royalties that it so desperately seeks. Among other things, it has filed infringement claims under the '275 patent, repeatedly threatened to bring infringement claims against others, stated that plaintiffs are infringing, and terminated licenses for failure to pay royalties under the '275 patent. (Biogen Opp. at 18–19.)

The circumstances of this case go far beyond the minimum controversy necessary to support the exercise of this Court's jurisdiction. "If the circumstances warrant, a reasonable apprehension may be found in the absence of *any* communication" from the patentee, and even "when a patentee first learns of [the declaratory judgment] plaintiff's conduct upon receipt of the complaint." *Arrowhead*, 846 F.2d at 736, 738 (emphasis added) (citing *Dewey & Almy*, 137 F.2d at 71). Here, Columbia had already received royalties from the MDL Plaintiffs, and clearly had the MDL Plaintiffs in its sights as it sought to extend their royalty obligations. A decision on the

viability of the '275 patent would not be “advisory” in any sense of the word, but rather would have an immediate and real effect on the parties’ contractual relations and business activities.

The cases cited by Columbia in an effort to excuse each of its pre-complaint actions involve parties that who had no existing or prior legal relationship, and none involved a licensor/licensee relationship.¹ These cases hold only that statements regarding potential infringement made for the sake of posturing during licensing negotiations do not generally create a reasonable apprehension of suit. *See, e.g., Leatherman Tool Group Inc. v. Bear MGC Cutlery Inc.*, 50 U.S.P.Q.2d 1856, 1856–57 (D. Or. Dec. 2, 1998); *see also Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 889 (Fed. Cir. 1992). Explicit demands for continuing royalties under an existing license agreement are significantly more threatening than any negotiation tactic, particularly against the background of Columbia’s public campaign to ensure a continued royalty stream on Plaintiffs’ products.

2. *There is an actual controversy with respect to activities after the filing of the Covenant.*

Columbia argues, illogically, that its conduct before the filing of the Covenant is “irrelevant,” and also that it has “done nothing since the filing of the Covenant to create any reasonable apprehension of an infringement suit.” (Reply at 9–10.) Prior to the Covenant, Plaintiffs had a reasonable apprehension that Columbia would sue with respect to any and all potentially infringing conduct. If the Covenant removes this apprehension at all, it does so only with respect to activity underway prior to September 1, 2004, while leaving open to attack a

¹ *See Teva Pharm. USA, Inc. v. Pfizer Inc.*, No. 03CV10167RGS, 2003 WL 22888848 (D. Mass. 2003) (no licensee/patentee relationship, and no statements made by the patentee to the putative infringer at all); *W. Interactive Corp. v. First Data Resources, Inc.*, 972 F.2d 1295, 1296 (Fed. Cir. 1992) (same); *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 886–87 (Fed. Cir. 1992) (no licensee/patentee relationship, and statements were made by the patentee in the context of licensing negotiations); *Charles Mach. Works, Inc. v. Digital Control Inc.*, 264 F. Supp. 2d 980, 986 (W.D. Okla. 2003) (same); *Leatherman Tool Group Inc. v. Bear MGC Cutlery Inc.*, 50 U.S.P.Q.2d 1856, 1856–57 (D. Or. Dec. 2, 1998) (same); *Kustom Signals, Inc. v. Applied Signals, Inc.*, No. 96-2274-JWL, 1996 WL 568817, at *1 (D. Kan. 1996) (same).

significant portion of Plaintiffs' post-September 1st activities. Where, as here, the covenant admittedly does not encompass ongoing activity that potentially infringes, the entire history is of central relevance. *See Sierra*, 363 F.3d at 1375 ("broad accusations" that "embraced all potentially infringing activities" not defeated by narrower covenant); *see also Arrowhead*, 846 F.2d at 736 (existence of a case or controversy turns on the "totality of the circumstances"). Moreover, in the Covenant itself, by expressly excluding conduct after September 1, 2004 and by expressly asserting its belief that the '275 patent is valid, enforceable and infringed, Columbia only *increased* the apprehension of an infringement suit.

3. *Columbia's newly stated intent to delay the filing of its infringement suit is irrelevant.*

Columbia asserts, also for the first time, that it will not *file* an infringement suit "while the Patent Office is considering the reissue application and the reexamination petition." (Reply at 8.) Columbia argues that there is no actual controversy because it has shown that it "does not *want* to be involved in any litigation over the '275 patent" *at this time*. (Reply at 1 (emphasis added), 7–8.)

By Order earlier today, the Court raised the question whether Columbia was:

willing to extend its covenant not to sue plaintiffs under the '275 patent to cover any and all methods and processes used, and products made, used, offered for sale, sold or imported by plaintiffs until the conclusion of the reissue and reexamination proceedings concerning the '275 patent currently pending before the United States Patent and Trademark Office.

Columbia answered that question in the negative through an exchange of letters with Biogen and Genzyme last week. Plaintiffs asked Columbia's counsel whether, in its new promise to delay the lawsuit, it was also promising not to seek in that lawsuit damages or royalties for the current period. Columbia refused to make that covenant. Columbia retained the right to establish, at a later date, accrued liability based on Plaintiffs' *current* activities. Letter from Claire Laporte to

David I. Gindler (Sept. 30, 2004), attached hereto as Tab 24; David I. Gindler to Claire Laporte (October 1, 2004), attached hereto as Tab 25.

Columbia's stated preference to file suit at a later date (and implicitly, in a court more to its liking) does not eliminate the actual controversy arising from the fact that Columbia believes Plaintiffs are currently infringing its patent. The very purpose of the Declaratory Judgment Act is to allow an interested person to resolve an actual controversy "without waiting until an adversary should see fit to begin an action." (Biogen Opp. at 23 (quoting Wright et al., *Federal Practice and Procedure* § 2751, at 457 (3d ed. 1998)).) Accordingly, while the second prong of the "reasonable apprehension" test requires that there be infringing *activity* in the foreseeable future, there is no requirement that the first prong—patentee's *lawsuit* challenging that activity—be practically imminent. *See Arrowhead*, 846 F.2d at 736 ("It would obviously be unrealistic to limit the required apprehension to one of imminent suit against plaintiff when defendant is exhibiting an intent to delay that suit until ... a trial date more convenient for defendant has arrived."); *Goodyear*, 824 F.2d at 956 (holding that even though the defendant may not presently bring suit, that is not dispositive of future intentions); *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, Civ. No. AMD-96-455, 1996 WL 432290 (D. Md. Apr. 4, 1996) (statement that there were no current plans to bring suit did not extinguish reasonable apprehension but rather merely suspended it, and did not divest the court of jurisdiction).

Finally, even if in response to this Court's Order of earlier today Columbia were to extend the Covenant further and to waive royalties and damages for the entire period until the completion of reexamination and reissue proceedings, there would still be an actual, justiciable controversy on these facts. Columbia has engaged in an unrelenting campaign to assure itself additional royalties based on the illicit '275 patent. Its expressed desire to avoid litigation until

after the PTO proceedings differs little from its earlier motion to stay this litigation pending those proceedings. Plaintiffs have no control over the timetable for those proceedings.

Columbia, on the other hand, can take steps to expedite the proceedings and is free to withdraw its reissue application at any time, thereby accelerating the date on which it could proceed to enforce the '275 patent against activities excluded from its Covenant. Indeed, upon completion of the PTO proceedings, Columbia would be free the very next day to assert the '275 patent with respect to the Plaintiffs' then-current activities. Under this scenario, while the timing of such a suit may be uncertain, Plaintiffs' continued apprehension of litigation is undeniable.

What is more, even if Plaintiffs were not currently accruing royalties or damages under the '275 patent, their affiliates are—Columbia reserves the right to sue affiliates at any time, including tomorrow, for damages all the way back to the issuance of the '275 patent. Columbia also expressly reserves the right to sue at any time on any patent that issues from its pending '159 patent application, even if the claims are *identical or substantially identical* to the '275 claims. Since Columbia chooses to leave these issues hanging over the heads of Plaintiffs for its own tactical advantage and to give it leverage in extracting settlements, Columbia can scarcely complain that Plaintiffs wish to proceed with the litigation. Otherwise, the Plaintiffs will be left, throughout the PTO proceedings, to confront important research, development, and business decisions regarding new products with long lead times, in the shadow of a patent that Columbia believes will be infringed by those products.

The Plaintiffs, and the industry as a whole, should not be forced to stand by helplessly awaiting a future lawsuit at a time and place of Columbia's choosing while Columbia continues its twenty-four year prosecution of patent claims directed at Plaintiffs' current and future

activities. *See 3M*, 929 F.2d at 670 (reversing dismissal of declaratory judgment action despite pending interference proceeding in the Patent and Trademark office).

C. *Gen-Probe* does not deprive this Court of subject matter jurisdiction.

Columbia further asserts that, “[u]nder *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), as licensees in good standing, [Plaintiffs] cannot have a reasonable apprehension that they will be sued for infringement of the licensed patent.” (Reply at 12.) In fact, this case has very little in common with *Gen-Probe*. As Columbia points out, Gen-Probe, the licensee, had “paid all royalties owed under the license agreement and remained a licensee in good standing during the litigation.” *Id.* Indeed, the Federal Circuit’s decision relied primarily upon the fact that Gen-Probe was a licensee in good standing that had not materially breached the license agreement. *Gen-Probe v. Vysis, Inc.*, 359 F.3d 1376, 1379, 1381 (Fed. Cir. 2004), *petition for cert. filed*, 2004 WL 1902970 (U.S. Aug. 20, 2004) (No. 04-260). The court determined that there was no actual controversy because the “license, unless materially breached, obliterated any reasonable apprehension of a lawsuit.” *Id.* at 1381.

Plaintiffs, by contrast, have never paid royalties under the ’275 patent, nor have they submitted the sales reports that the license agreement requires at the close of each quarter, which are expressly required whether or not royalties are due. Columbia asserted the failure to provide quarterly reports as grounds for termination last March, and in its September 13, 2004, letters it expressly preserved those grounds. (Biogen Opp. at 25.)² Assuming that Plaintiffs’ licenses are now reinstated after having previously been terminated, Plaintiffs are not licensees “in good standing” under the express terms of the licenses. The license agreements themselves define both non-payment of royalties and failure to submit the reports as “material breach,” and, as

² Columbia’s claim that it “rejects” this interpretation of the license agreement (Reply at 15 n.13) does not alter the plain language of the contract.

noted, Columbia based its notices of termination upon its conclusion that these very failures put Plaintiffs in material breach. Biogen License § 5(b) (Tab 2 to Appendix to Opposition of Biogen Idec MA Inc. and Genzyme Corporation to Columbia University's Motion to Dismiss ("Biogen App.)); Genzyme License § 5(b) (Tab 3 to Biogen App.); Biogen Termination Letter (Tab 9 to Biogen App.); Genzyme Termination Letter (Tab 10 to Biogen App.).

In addition, the Plaintiffs have made it perfectly clear that they believe the '275 patent to be invalid and unenforceable and thus will not pay any past, present, or future royalties short of a court ruling upholding its validity and enforceability. *See* Compl. ¶ 1 ("Columbia has no lawful right to receive royalties from its licensees ... based on its newly-issued cotransformation patent because that patent is invalid and unenforceable."); *id.* ¶ 38 ("The plaintiffs contend that they have no obligation to pay [royalties under the '275 patent] because ... the '275 patent is invalid and unenforceable."). Under governing New York law, the prospective nonpayment of royalties may be found to be an anticipatory breach. *See* Biogen License § 10 (Tab 2 to Biogen App.); Genzyme License § 10 (Tab 3 to Biogen App.); *see also Wester v. Casein Co. of Am.*, 100 N.E. 488, 490 (N.Y. 1912); *Long Island Lighting Co. v. State*, 392 N.Y.S.2d 559, 561 (N.Y. Ct. Cl. 1977); N.Y. Jur. 2d: Contracts §§ 443, 445, 446, 448; 15 Samuel Williston & Richard A. Lord, *A Treatise on the Law of Contracts* § 43:17 (4th ed. 2000) (prospective nonperformance of a contractual duty "constitutes a total breach of the contract, even though it is not accompanied by or preceded by a present breach by nonperformance"); *Rubber Trading Co. v. Manhattan Rubber Mfg. Co.*, 116 N.E. 789, 790 (N.Y. 1917). This, too, distinguishes the facts here from those in *Gen-Probe*.

Moreover, Plaintiffs must determine, in an atmosphere of uncertainty over the status of their licenses and the '275 patent, whether to pay the required annual fee that will come due

January 1, 2005, less than three months from today. Biogen License § 3(b) (Tab 2 to Biogen App.); Genzyme License § 3(b) (Tab 3 to Biogen App.). This Court has ruled that there is a likelihood of success on Plaintiffs' claim that the '275 patent is unenforceable due to prosecution laches. Aug. 13, 2004 Mem. & Order, at 19–23 (MDL Docket No. 84). If the '275 patent is unenforceable for prosecution laches, any patent issuing from the pending '159 application, as well as any reissue patent, likewise will be unenforceable. This imminent contractual duty to pay itself gives rise to an actual controversy as to the enforceability of the '275 patent and related applications. *See Keener Oil & Gas Co. v. Consolidated Gas Utils. Corp.*, 190 F.2d 985, 989 (10th Cir. 1951) (“party is not compelled to wait until he has committed an act which the other party asserts will constitute a breach, but may seek relief by declaratory judgment ... in order to avoid the risk of damages or other untoward consequences”).

Accordingly, unlike *Gen-Probe*, it cannot be said that there are licenses in place that “obliterate[] any reasonable apprehension of a lawsuit.” Assuming the licenses are in effect today, Columbia has not lost the right to terminate the licenses in the future. Columbia has not waived its right to royalties, but rather reserves the right to demand royalties for any activity not covered by its Covenant. In its Reply brief, it says it does not intend to terminate for failure to submit quarterly reports, but *only* with respect to periods as to which it decides not to claim that royalties are due. (Reply at 15 n.13.) As in *Bard*, Columbia's carefully limited promises do not eliminate the actual controversy surrounding the validity and enforceability of the patent. *Bard*, 716 F.2d at 876, 881 (neither promise not to sue nor existence of license totally removed the threat of litigation); *see also Fina*, 141 F.3d at 1483–84 (promise not encompassing all forms of party's potential infringement did not remove threat of litigation).

Without acknowledging the key distinctions between the facts here and the facts in *Gen-Probe*, Columbia simply assumes that its reinstatement of the licenses divests this Court of subject matter jurisdiction. (Reply at 12.) Plaintiffs have already pointed out that the existence of a license does not preclude jurisdiction. *See Bard*, 716 F.2d at 875, 880–81 (upholding declaratory judgment jurisdiction where licensee had stopped paying royalties, even though patentee had not terminated license); *see also Lear*, 395 U.S. at 670–71. On the contrary, since the Supreme Court overturned the doctrine of licensee estoppel in *Lear*, licensees have been allowed to challenge licensed patents on invalidity and unenforceability grounds. *See* 395 U.S. at 670–71. Like any other plaintiff, a licensee need only show that there is an Article III “case” or “controversy” under the “totality of the circumstances” in order to maintain declaratory judgment jurisdiction. *See Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *Aetna*, 300 U.S. at 239–42; *Bard*, 716 F.2d at 880–81.

Indeed, there are numerous examples of courts exercising jurisdiction over patent challenges even in the face of a paid-up license. *See Altvater v. Freeman*, 319 U.S. 359, 364 (1943) (“The fact that royalties were being paid did not make this a ‘difference or dispute of a hypothetical or abstract character.’ A controversy was raging, even apart from the continued existence of the license agreement. ... That controversy concerned the validity of the reissue patents.”); *Engel Indus., Inc. v. Lockformer Co.*, 166 F.3d 1379, 1381 (Fed. Cir. 1999) (exercising jurisdiction where a licensee paid royalties throughout the litigation); *Precision Shooting Equip. Co. v. Allen*, 646 F.2d 313, 317–18 (7th Cir. 1981) (licensee in good standing challenged a licensed patent through a declaratory judgment action); *Warner-Jenkinson Co. v. Allied Chem. Corp.*, 567 F.2d 184, 187 n.4 (2d Cir. 1977) (same)³; *cf. Cordis Corp. v. Medtronic*,

³ The Second Circuit’s decision in *Warner-Jenkinson*, which held that even a licensee in good standing could present an actual controversy sufficient to maintain a declaratory judgment action, was expressly adopted in *Bard*,

Inc., 780 F.2d 991, 993 (Fed. Cir. 1985) (refusing to enjoin termination of license on the ground that licensee had the option of remaining in good standing by paying royalties and recouping them upon judgment of invalidity).

Columbia's reliance on *Gen-Probe* to eliminate the reasonable apprehension of suit here is unavailing. Moreover, its transparent attempt selectively to pick off plaintiffs whose cases originated in the District of Massachusetts should be rejected. Columbia says it has reinstated the licenses of Biogen, Genzyme, and Abbott Bioresearch Center, Inc.—the three parties to the original District of Massachusetts action—but no other plaintiffs. The reason can only be to shift the balance so that a larger proportion of the cases originated elsewhere, in the hopes of undoing the ruling of the MDL Panel and reviving its previous forum-shopping maneuvers.

D. Plaintiffs' new contract and tort claims, upon consolidation, will provide an independent basis for jurisdiction.

Plaintiffs have filed a new action in this Court in which they assert claims arising out of Columbia's improper leverage of its invalid patent and abusive litigation tactics. Three of the new claims—abuse of process, breach of contract and violation of Mass. Gen. Laws ch. 93A—do not require a showing that there is a reasonable apprehension of an infringement suit. Each of these claims asserts, as an element of the claim, that the '275 patent is invalid and unenforceable. In addition, Biogen Idec Inc. has sued for a declaratory judgment of invalidity and unenforceability, based upon its reasonable apprehension of suit by Columbia. Biogen Idec Inc. has never had a license from Columbia and is expressly excluded from the Covenant. The new suit is a “tag along action” under the MDL procedures, and Plaintiffs have asked that the new

716 F.2d at 880, which cannot be overruled by the *Gen-Probe* panel. See *El-Shifa Pham. Indus. Co. v. United States*, 378 F.3d 1346, 1353 (Fed. Cir. 2004); see also Fed. Cir. Rule 35(a)(2) (“[O]nly the court en banc may overrule a binding precedent”).

action be consolidated for all purposes with this action. These claims provide further support for the Court's exercise of jurisdiction to resolve this dispute.

E. This Court should exercise its jurisdiction to resolve this important dispute and maintain an expedited schedule.

A declaratory judgment action is not a permissive action that may be dismissed in absolute judicial discretion. "When there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory action is not subject to dismissal." *Genentech, Inc. v. Eli Lilly and Co.*, 998 F.2d 931, 936-37 (Fed. Cir. 1993) (abuse of discretion to dismiss declaratory judgment claims), *abrogated in part on other grounds by Wilton v. Seven Falls Co.*, 515 U.S. 277, 287 (1995). In *3M*, for example, the Federal Circuit reversed a district court's decision to decline exercising declaratory judgment jurisdiction, finding that the lower court gave too little weight to the ever-growing potential liability of the declaratory judgment plaintiff and the resulting harm. *See* 929 F.2d at 673-74.

Here, resolution of Plaintiffs' declaratory judgment claims is the only way to remove the acute uncertainty under which Plaintiffs have been forced to operate since the issuance of the '275 patent in 2002. A declaratory judgment is necessary to put an end to Columbia's "scare-the-customer-and-run tactics" – conduct that the Federal Circuit condemned in *Arrowhead*. If this case is dismissed, the public may be forced to pay tribute to a "would-be monopolist[] without any need or justification," the concern expressed by the Supreme Court in *Lear*.

This case does not present any concerns that have been held to justify the discretionary dismissal of a declaratory judgment action. *Cf. EMC Corp. v. Norand Corp.*, 89 F.3d 807, 815 (Fed. Cir. 1996) (party brought declaratory judgment action to use as leverage in licensing negotiations with patentee); *Davox Corp. v. Digital Sys. Int'l, Inc.*, 846 F Supp. 144, 148

(D. Mass. 1993) (party brought declaratory judgment action in order to preempt suit by patentee and secure a more favorable forum). On the contrary, the dismissal of this action would permit *Columbia* to take advantage of the very strategies disapproved by the courts in *EMC* and *Davox*—unfair leverage in negotiations and transparent forum-shopping.

III. CONCLUSION

Columbia insists that it has given enough, in the form of its Covenant, to avoid this Court's scrutiny of its patent. Columbia underestimates the power of Article III courts. Given the history between these parties, and the ongoing activity set out in Plaintiffs' sworn and uncontested declarations, this Court has jurisdiction to consider the validity and enforceability of the '275 patent, even apart from Plaintiffs' newly filed claims that put the validity and unenforceability of the patent into dispute for other reasons. The Court should exercise that jurisdiction to put an end to Columbia's use of this illegal patent to stifle economic activity and seek to extract unjustified financial settlements.

It is no accident that Columbia's Covenant has so many defects. Columbia purposely limited its Covenant so as to preserve the right to sue Plaintiffs for royalties and/or damages at a time and place that better suits its own strategic plan for the enforcement of the '275 patent. It also did so to maximize its leverage to extract settlements based upon the apprehension of Plaintiffs that their current and planned activity remains exposed to continually accruing liability.

This Court has the power to resolve this critically important dispute, and is on course to do so in an expeditious manner. Columbia's Motion to Dismiss should be denied.

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Respectfully submitted,

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